APPENDIX I 510(k) Summary

A. Submitter Information

1. Contact Name:

   Jason Smith, Regulatory Affairs Associate

2. Contact Address:

   Baxter Healthcare Corporation
   Edwards Critical-Care Division
   17221 Red Hill Avenue
   Irvine, CA 92614-5686

3. Contact Telephone:

   (949) 250-2662

4. Contact Fax Number:

   (949) 756-4021

B. Device Information

1. Trade Name:

   Swan-Ganz® Synthetic ControlCath™ Thermodilution Catheters

2. Common or Usual Name:

   Flow-Directed Pulmonary Artery Thermodilution Catheters

3. Device Classification and Classification Name:

   Class II (74 DYG, 21 CFR 870.1240 Flow-directed catheter)

4. Predicate Device Identification:

Swan-Ganz® Improved Torque, Hi-Shore, 7 French, True Size, Thermodilution Catheter (K915726)

5. Device Description:

Like the predicate device, the subject catheters provide diagnostic tools for the physician to rapidly determine hemodynamic pressures and cardiac output when used with a compatible cardiac output computer. Swan-Ganz® Synthetic ControlCath™ Thermodilution Catheters are manufactured using a 7 French radiopaque, four-lumen tube extruded from a blend of polymer materials. There is a distal "through" lumen, injectate lumen, balloon inflation lumen, and a lumen dedicated to the thermistor and its connecting wires.

6. Intended Use:

The Swan-Ganz® Synthetic ControlCath™ Thermodilution Catheters, like the predicate device, are intended for use in the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination and for infusing solutions. In addition, the distal port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction.

7. Technological Comparison of Subject Device to Predicate Device:

The subject catheters and predicate device are identical in components, materials, construction, and intended use with the exception that the subject catheters are manufactured with a synthetic

balloon while the predicate device is manufactured with a natural rubber latex balloon.

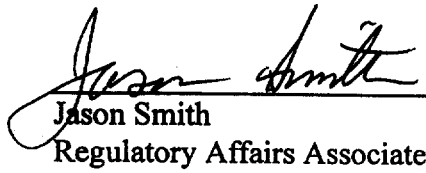
8. Summary of Non-Clinical Tests and Conclusions:

Extensive *in vitro* performance testing and biocompatibility evaluations were conducted comparing the synthetic balloon of the subject catheter to the natural rubber latex balloon of the predicate device. All testing demonstrated that the synthetic balloon is substantially equivalent to the natural rubber latex balloon.

9. Summary of Clinical Tests and Conclusions:

Clinical testing was not required to establish the substantial equivalence of the subject catheter to the predicate device.

C. Submitter's Signature and Date of Summary Preparation



Jason Smith
Regulatory Affairs Associate

3/30/00
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2000

Mr. Jason Smith
Regulatory Affairs Associate
Baxter Healthcare Corporation
17221 Red Hill Avenue
Irvine, CA 92614-5686

Re: K001063
Swan-Ganz™ Synthetic ControlCath™ Thermodilution Catheters
Regulatory Class: II (Two)
Product Code: DYG
Dated: June 26, 2000
Received: June 27, 2000

Dear Mr. Smith:

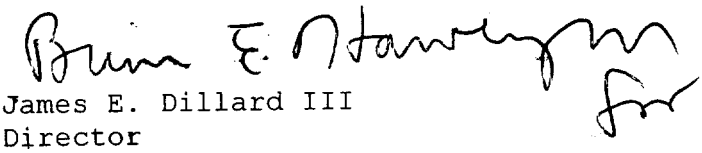
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Reference: **510(k) Notification for the Swan-Ganz® Synthetic ControlCath™ Thermodilution Catheters**

The Swan-Ganz® Synthetic ControlCath™ Thermodilution Catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination and for infusing solutions. The distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient and intrapulmonary shunt fraction.

Brian E. Harrington
Tam A. Pe for Christopher Sloan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001063